K070242
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5 510(K) SUMMARY

MAY 15 2007

Applicant:

Biosense Webster, Inc.
3333 Diamond Canyon Rd.
Diamond Bar, CA 91765
USA
Phone: +1-800-729-7272
Fax: +1-909-839-8804

Date: January 24, 2007

Contact Person:

Melissa Crisostomo
Specialist, Regulatory Affairs

Proprietary Device Name: SOUNDSTAR™ 3D Ultrasound Catheter

Common Device Name: Electrophysiologic Mapping/Ultrasound Catheter, Class II Device

Classification Name:

Classification Name	CFR#	Product Code
Electrode Recording Catheter	21 CFR 870.1220	DRF
Diagnostic Intravascular Catheter	21 CFR 870.1200	DQO
Diagnostic Ultrasound Catheter	21 CFR892.1570	ITX

Predicate Devices: ACUSON AcuNav™ 10F Diagnostic Ultrasound Catheter 510(k) K033650

Biosense Webster NAVISTAR® Diagnostic catheter 510(k) K954390

Manufacturer:

Biosense Webster, Inc.
3333 Diamond Canyon Road
Diamond Bar, CA 91765

5.1 Substantially Equivalent To

The Biosense Webster SOUNDSTAR™ 3D Ultrasound Catheter is substantially equivalent to a combination of the ACUSON AcuNav™ 10F Diagnostic Ultrasound Catheter 510(k) K033650, cleared February 24, 2004 for whole heart for Sequoia, Aspen and Cypress Ultrasound Systems and the Biosense Webster NAVISTAR® Diagnostic catheter 510(k) K954390, cleared December 21, 1995.

5.2 Intended Use

The Biosense Webster SOUNDSTAR™ 3D Ultrasound Catheter and related accessory devices are indicated for intra-cardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart. When used with the CARTO® XP EP Navigation System Version 9 or greater, the SOUNDSTAR™ 3D Ultrasound Catheter provides location information.

5.3 General Device Description

The Biosense Webster SOUNDSTAR™ 3D Ultrasound Catheter is a 90 cm 10F IntraCardiac Echo (ICE) Catheter with an acoustic array identical to the ACUSON AcuNav™ 10F Diagnostic Ultrasound Catheter. The catheter has a location sensor (providing location information to the CARTO® EP XP Navigation System Version 9 – 510(k) submitted separately) and an ultrasound transducer (acquiring real time ultrasound images) embedded in the tip.

The SOUNDSTAR™ 3D Ultrasound Catheter has a bifurcated 'tail' originating from its handle (see Figure 1). One leg terminates in the SOUNDSTAR tab connector, which connects via a Swiftlink™ cable to an ultrasound system (ACUSON Sequoia™ Ultrasound System or the ACUSON Cypress™ Ultrasound System, cleared under 510(k) K052410 and 510(k) K052331 respectively). The other leg terminates in the CARTO Hypertronic connector, which connects via a Patient Interface Unit (PIU) extension cable to the CARTO® XP EP Navigation System Version 9 (510(k) submitted bundled with the SOUNDSTAR™ 3D Ultrasound Catheter submission).

Figure 1: SOUNDSTAR 3D™ Handle with bifurcated connectors

The Sequoia and Cypress Ultrasound Systems were designed to acquire two dimensional (2D) ultrasound (U/S) images and display them. The SOUNDSTAR™ 3D Ultrasound Catheter connects to either of these

ultrasound systems via the appropriate SwiftLink connector cable. The U/S images are Vector™ images for wide angle viewing of the heart anatomy. These systems are used to image the anatomy of the heart and also visualize blood flow through Doppler imaging. They are also used to visualize other catheters and devices in the heart.

The imaging software in the Sequoia and Cypress U/S systems that currently drives AcuNav Catheters will be the same software that drives the SOUNDSTAR™ 3D Ultrasound Catheter.

The acoustic array used in the SOUNDSTAR™ 3D Ultrasound Catheter is identical to the acoustic array currently used in the AcuNav Catheter.

The CARTO® XP EP Navigation System Version 9 is designed to acquire, analyze, and display electro-anatomical maps of the human heart. The maps are reconstructed using the combination of information gathered from the integration of intracardiac electrograms with their respective endocardial locations. Maps may be displayed as electrical activation maps, electrical propagation maps, electrical potential maps, impedance maps and chamber geometry maps. The acquired patient signals, including body surface ECG and intracardiac electrograms may also be displayed in real-time on the display screen.

The SOUNDSTAR™ 3D Ultrasound Catheter is compatible with the CARTO® XP EP Navigation System Version 9, (Version 8 cleared under 510(k) K042999).

The SOUNDSTAR™ 3D Ultrasound Catheter, when connected to the CARTO® XP EP Navigation System Version 9, and the Sequoia or the Cypress Ultrasound Systems, will provide real-time integration of ultrasound images with CARTO electromagnetic acquired maps.

For a complete description of the Sequoia Ultrasound System, the Cypress Ultrasound System, or the CARTO® XP EP Navigation System Version 8, please refer to cleared 510(k) submissions, 510(k) K052410, 510(k) K052331 and 510(k) K042999 respectively.

5.4 Performance Data and Conclusion

The SOUNDSTAR™ 3D Ultrasound Catheter underwent extensive bench and electrical testing. The catheter passed all intended criteria in accordance with appropriate acceptance criteria and standards.

The non-clinical studies demonstrate that the SOUNDSTAR™ 3D Ultrasound Catheter is safe and effective for:

- Intra-cardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology.
- Visualization of other devices in the heart.
- Acquisition of location information for CARTO mapping.

The SOUNDSTAR™ 3D Ultrasound Catheter was also tested under simulated use conditions in animals.

The studies establish equivalence of the SOUNDSTAR™ 3D Ultrasound Catheter to the predicate devices, the NAVISTAR Diagnostic catheter and the AcuNav 10F Ultrasound Catheter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 15 2007

Biosense Webster
c/o Neelu Medhekar
Manager, Regulatory Affairs
3333 Diamond Canyon Rd.
Diamond Bar, CA 91765

Re: K070242
Trade/Device Name: SoundStar 3D Ultrasound Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic intravascular catheter
Regulatory Class: Class II
Product Code: OBJ
Dated: April 6, 2007
Received: April 9, 2007

Dear Ms. Medhekar:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

B Zuckerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4 INDICATIONS FOR USE STATEMENT

510(k) No (if known): K070242

Device Name: SOUNDSTAR™ 3D ULTRASOUND CATHETER

Indications for Use:

The Biosense Webster SOUNDSTAR™ 3D Ultrasound Catheter and related accessory devices are indicated for intra-cardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart. When used with the CARTO® XP EP Navigation System Version 9 or greater, the SOUNDSTAR™ 3D Ultrasound Catheter provides location information.

Prescription Use (Part 21 CFR 801 Subpart D)	___X___	AND/OR	Over-The-Counter Use (21 CFR 801 Subpart C)	_____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

B Runnumon

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K070242

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